DETAILED ACTION

Claims 1- 7, 9-21 are pending.

Applicants have elected Group I of the restriction, Claims 1-7, 11-16, 19 and 20 drawn to a formula I where in Y is a N.

Claim Rejections - 35 USC § 102(e)

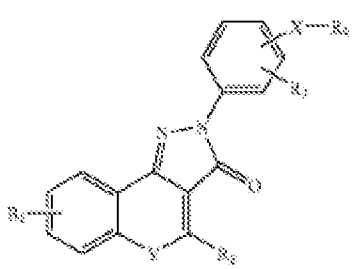
> the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 11-16, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by US 7291612 and US 7081456. Mattews et al .

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

See claims of the US 7291612

1. A compound of formula (I) or a pharmaceutically or veterinarily acceptable salt thereof:



(I)

wherein

R_1 and R_3 independently represent H; F; Cl; Br; —NO_2; —CN; C_1-C_3 alkyl optionally substituted by F or Cl; or C_1-C_6 alkoxy optionally substituted by F;

R_2 represents H, or optionally substituted C_1-C_6 alkyl, C_3-C_7 cycloalkyl or optionally substituted phenyl;

Y represents —O—, —S—, N-oxide, or —$N(R_5)$— wherein R_5 represents H or C_1-C_3 alkyl;

X represents a bond or a divalent C_1-C_3 alkylene radical;

R_4 represents —$NR_7C(=O)R_8$, —$NR_7C(=O)OR_8$, —$NHC(=O)NHR_8$ or —$NHC(=S)NHR_8$ wherein:

when R_4 represents —$NR_7C(=O)R_8$ or —$NR_7C(=O)OR_8$, R_8 represents H, or a radical of formula —$(Alk)_b$-Q wherein b is 0 or 1 and Q represents H; —CF_3; —OH; —SH; —NR_9R_9 wherein each R_9 may be the same or different; an ester group; or an optionally substituted phenyl, C_3-C_7 cycloalkyl, C_5-C_7 cycloalkenyl or heterocyclic ring having from 5 to 8 ring atoms;

when R_4 represents —$NHC(=O)NHR_8$ or —$NHC(=S)NHR_8$, R_8 represents a radical of formula —$(Alk)_b$-Q wherein b is 1 and Q represents —CF_3; —OH; —SH; —NR_9R_9 wherein each R_9 may be the same or different; an ester group; or an optionally substituted phenyl, C_3-C_7 cycloalkyl, C_5-C_7 cycloalkenyl or heterocyclic ring having from 5 to 8 ring atoms;

where Alk is a divalent straight chain or branched C_1-C_{12} alkylene, C_2-C_{12} alkenylene or C_2-C_{12} alkynylene radical which may be interrupted by one or more non-adjacent ---O---, ---S--- or ---N(R_8)--- radicals wherein R_8 represents H or C_1-C_4 alkyl, C_3-C_8 alkenyl, C_3-C_4 alkynyl, or C_3-C_8 cycloalkyl, and

R_7 represents H or C_1-C_8 alkyl; or when taken together with the atom or atoms to which they are attached R_6 and R_7 form an optionally substituted heterocyclic ring having from 5 to 8 ring atoms.

2. A compound as claimed in claim 1 wherein R_1 is H, F, Cl, methyl or methoxy.

3. A compound as claimed in claim 1 wherein R_2 is H, methyl, cyclopropyl, phenyl, or fluoro-, chloro-, methyl-, or methoxy-substituted phenyl.

4. A compound as claimed in claim 1 wherein R_3 is H, F, Cl, methyl, or methoxy.

5. A compound as claimed in claim 1 wherein Y is ---O---, ---S---, or ---N(R_5)--- wherein R_5 represents H or methyl.

6. A compound as claimed in claim 1 wherein X is a bond, or a ---CH_2--- or ---CH_2CH_2--- radical.

7. A compound as claimed in claim 1 wherein R_4 represents ---$NR_6C(=O)R_9$, ---$NR_6C(=O)OR_9$, ---NHC(=O)NHR_9 or ---NHC(=S)NHR_9 wherein:

when R_4 represents ---$NR_6C(=O)R_9$ or ---$NR_6C(=O)OR_9$, R_6 is H or a radical of formula ---Alk_b-Q wherein

b is 0 or 1 and

Alk is a ---$(CH_2)_n$---, ---$CH(CH_2)_m$$CH_3$)$(CH_2)_p$---, ---$CH((CH_2)_m$$CH_3$)$(CH_2)_p$$CH_3$)$(CH_2)_p$---, ---$(CH_2)_n$---O---$(CH_2)_m$---, or ---$(CH_2)_n$---O---$(CH_2)_m$---O---$(CH_2)_m$---, radical where n is 1, 2, 3 or 4 and m and p are independently 0, 1, 2, 3 or 4, and Q represents H, ---OH, ---$COOCH_3$, phenyl, cyclopropyl, cyclopentyl, cyclohexyl, pyridyl, furyl, thienyl, or oxazolyl, and

when R_4 represents ---NHC(=O)NHR_9 or ---NHC(=S)NHR_9, R_9 is a radical of formula ---Alk_b-Q wherein

b is 1 and

Alk is a ---$(CH_2)_n$---, ---$CH(CH_2)_m$$CH_3$)$(CH_2)_p$---, ---$CH((CH_2)_m$$CH_3$)$(CH_2)_p$$CH_3$)$(CH_2)_p$---, ---$(CH_2)_n$---O---$(CH_2)_m$---, or ---$(CH_2)_n$---O---$(CH_2)_m$---O---$(CH_2)_m$---, radical, where n is 1, 2, 3 or 4 and m and p are independently 0, 1, 2, 3 or 4, and Q represents ---OH, ---$COOCH_3$, phenyl, cyclopropyl, cyclopentyl, cyclohexyl, pyridyl, furyl, thienyl, or oxazolyl, and

R_7 is H, or when taken together with the nitrogen atom to which they are attached R_6 and R_7 form a pyrrolidine-2-one or pyrrolidine-2,5-dione ring.

8. A compound as claimed in claim 1 wherein R_1 is H, F, or Cl; R_2 is H; R_3 is H, F, or Cl; Y is ---NH---; X is a bond; and R_4 represents ---$NR_6C(=O)R_9$, ---$NR_6C(=O)OR_9$ or ---NHC(=O)NHR_9 wherein:

when R_4 represents ---$NR_6C(=O)R_9$ or ---$NR_6C(=O)OR_9$, R_6 is H or a radical of formula ---Alk_b-Q wherein

b is 0 or 1 and

Alk is a ---$(CH_2)_n$---, ---$CH(CH_2)_m$$CH_3$)$(CH_2)_p$---, ---$CH((CH_2)_m$$CH_3$)$(CH_2)_p$$CH_3$)$(CH_2)_p$---, ---$(CH_2)_n$---O---$(CH_2)_m$---, or ---$(CH_2)_n$---O---$(CH_2)_m$---O---$(CH_2)_m$---, radical where n is 1, 2, 3 or 4 and m and p are independently 0, 1, 2, 3 or 4, and Q represents H, ---OH, ---$COOCH_3$, phenyl, cyclopropyl, cyclopentyl, cyclohexyl, pyridyl, furyl, thienyl, or oxazolyl, and

when R_4 represents ---NHC(=O)NHR_9, R_9 is a radical of formula ---Alk_b-Q wherein

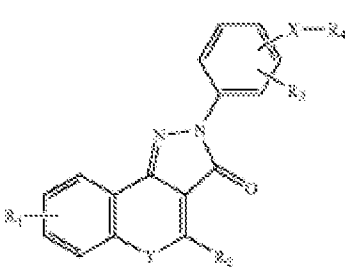
b is 1 and

Alk is a ---$(CH_2)_n$---, ---$CH(CH_2)_m$$CH_3$)$(CH_2)_p$---, ---$CH((CH_2)_m$$CH_3$)$(CH_2)_p$$CH_3$)$(CH_2)_p$---, ---$(CH_2)_n$---O---$(CH_2)_m$---, or ---$(CH_2)_n$---O---$(CH_2)_m$---O---$(CH_2)_m$---,

And US 7081456.

The invention claimed is:

1. A compound of formula (I) or a pharmaceutically or veterinarily acceptable salt thereof:



(I)

wherein:

R_1 and R_3 independently represent H; F; Cl; Br; —NO_2; —CN; C_1–C_6 alkyl optionally substituted by F or Cl; or C_1–C_6 alkoxy optionally substituted by F;

R_2 represents H, or optionally substituted C_1–C_6 alkyl, C_3–C_7 cycloalkyl or optionally substituted phenyl;

Y represents —O—, —S—, N-oxide, or —N(R_5)— wherein R_5 represents H or C_1–C_6 alkyl;

X represents a bond or a divalent C_1–C_6 alkylene radical;

R_4 represents —C(=O)NR_6R_7, wherein

R_6 represents a radical of formula -(Alk)$_\delta$-Q wherein δ is 1 and

Alk is an optionally substituted divalent straight chain or branched C_1–C_{12} alkylene, C_2–C_{12} alkenylene or C_2–C_{12} alkynylene radical which may be interrupted by one or more non-adjacent —O—, —S— or —N(R_8)— radicals wherein R_8 represents H or C_1–C_4 alkyl, C_3–C_4 alkenyl, C_3–C_4 alkynyl, or C_3–C_5 cycloalkyl, and

Q represents H; —CF_3; —OH; —SH; —NR_9R_9 wherein each R_9 may be the same or different; an ester group; or an optionally substituted phenyl, C_3–C_7 cycloalkyl, C_3–C_7 cycloalkenyl or heterocyclic ring having from 5 to 8 ring atoms; and

R_7 represents H or C_1–C_6 alkyl; or when taken together with the atom or atoms to which they are attached R_6 and R_7 form an optionally substituted heterocyclic ring having from 5 to 8 ring atoms.

2. A compound as claimed in claim 1 wherein R_1 is H, F, Cl, methyl or methoxy.

3. A compound as claimed in claim 1 wherein R_2 is H, methyl, methoxy, cyclopropyl, phenyl, or fluoro-, chloro-, methyl, or methoxy-substituted phenyl.

4. A compound as claimed in claim 1 wherein R_3 is H, F, Cl, methyl, or methoxy.

5. A compound as claimed in claim 1 wherein Y is —O—, —S—, or —N(R_5)—wherein R_5 represents H or methyl.

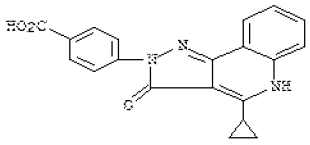
6. A compound as claimed in claim 1 wherein X is a bond, or a —CH_2— or —CH_2CH_2— radical.

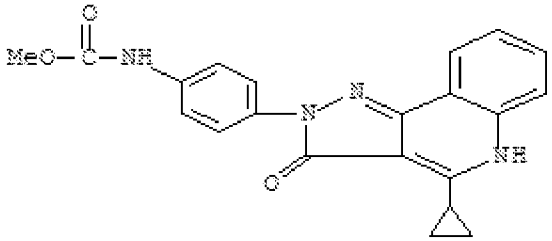
7. A compound as claimed in claim 1 wherein R_4 represents —C(=O)NHR_{6a}, wherein R_{6a} is a radical of formula -Alk$_\delta$-Q wherein

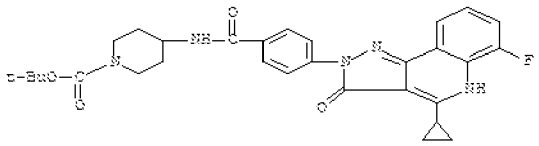
Some of species given are

RN 702706-05-6 CAPLUS

CN Benzoic acid, 4-(4-cyclopropyl-3,5-dihydro-3-oxo-2H-pyrazolo[4,3-c]quinolin-2-yl)- (CA INDEX NAME)







These compounds read on the applicants when R2 is a cycloalkyl, R3 is H , X is a bond .

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 11-16 , 19 and 20 are rejected on the ground of nonstatutory double

patenting over claims 1-8 of U. S. Patent No. 7291612 , and claims 1-7 of US 7081456 .

Claims 1-7, 11-16, 19 and 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, of U.S. Patent No. US 7291612 and claims 1-7 of US Patent No. 7081456.. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is overlapping subject matter.

See rejection above.

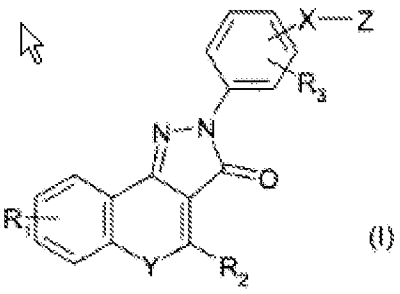
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 11-16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 03/004495 (filing date) Bjork et al. US 6642249. (July 2001)

Applicants claims are drawn to compounds and pharmaceutical compositions of the formula

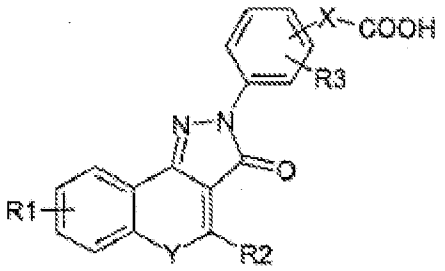


(I)

wherein Z is a COOH or an ester thereof., R2 is an optionally substituted cycloalkyl or a phenyl

Scope & Content of Prior Art MPEP 2141.01

WO 03/004495 Bjork et al teaches compounds of the formula



(I)

Y is a NR4, R2 is a H or a lower alkyl. (wherein lower alkyl meaning includes cyclic alkyl groups having 1-6 carbon atoms (see line 9 and 10 page 4 of the reference.

Difference between Prior Art and the claims MPEP 2141.02

Even though WO '495 Bjork et al teaches the same core of the same use, it generically teaches R2 being a cycloalkyl, no species have been made.

Prima Facie Obviousness , Rational and Motivation MPEP 2142-2413

Bjork et al generically teaches the same core with Z being a COOH or its ester.

Even though no species have been made the teaching that a cycloalkyl ring can be present at the R2 substitution and still retain the properties. Thus motivating a person of skill in the art to substitute a carbocyclic ring for R2 (cycloalkyl or a phenyl) and still have some

expectation of success that the compounds would have activity. KSR International v Telflex Inc.

Conclusion

Claims 1-7, 11-16, 19 and 20 are not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/
Primary Examiner, Art Unit 1625

R.D.
September 22, 2008